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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/453,109	12/02/1999	MARK R. PRAUSNITZ	BVTP-P01-539	2183

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EXAMINER	
KREMER, MATTHEW J	

ART UNIT	PAPER NUMBER
3736	15

DATE MAILED: 05/13/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/453,109	Applicant(s) PRAUSNITZ ET AL.	
	Examiner Matthew J Kremer	Art Unit 3736	

-- *The MAILING DATE of this communication appears on the cover sheet with the correspondence address* --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 June 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-46* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-46* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☒ The proposed drawing correction filed on *26 December 2001* is: a)☒ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 6/17/2002 has been entered.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. Claims 1-2, 9-23, 25-28, 31-32, 35, and 37-46 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent 6,334,856 to Allen et al. The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e) This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37

CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Allen et al. discloses a microneedle device that can be used for the controlled sampling of biological fluid in a minimally-invasive manner. (column 2, lines 55-58 of Allen et al.). The microneedles have a width that is between 10 nm to 1 mm, preferably between 10-100 microns. (column 5, lines 38-549 of Allen et al.). The microneedles have a length between 1 micron and 1 mm, preferably between 30-200 microns. (column 5, lines 51-58 of Allen et al.). The device includes a substrate to which the microneedles are attached or integrally formed and a reservoir. (column 4, lines 33-38 of Allen et al.). In regard to claims 2 and 12, the transportation of molecules through the microneedles can be controlled using various combinations of valves, pumps, sensors, actuators, and microprocessors. (column 7, lines 4-12 of Allen et al.). In regard to claim 9, the device may have a plurality of compartments. (column 8, lines 52-65 of Allen et al.). In regard to claim 10, Fig. 1B of Allen et al. shows a 3D array of microneedles. In regard to claim 11, an adhesive layer is used to facilitate contact with the biological barrier. (column 8, lines 41-49 of Allen et al.). In regard to claims 14-15, 18, and 22, a biosensor in the collection chamber or in the microneedle is disclosed. (column 28, lines 8-19 of Allen et al.). In regard to claims 16-17, 20-21, 23, and 30, a sensor inside the microneedle can detect glucose with glucose oxidase. (column 7, line 66 to column 8, line 29 of Allen et al.). In regard to claim 25, there is a hole disclosed in the side of the microneedle. (column 6, lines 42-51 of Allen et al.). In regard to claims 13 and 26, there

are transport control methods such as removable barriers and a material to modulate the flow. (column 7, lines 47-60 of Allen et al.). In regard to claims 38-40 and 42-44, the microneedle can be essentially metal. (column 13, lines 29-44 of Allen et al.) or hollow (column 11, lines 49-65 of Allen et al.).

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claims 3-5, 7, 29, and 33-34 are rejected under 35 U.S.C. 103(a) as being obvious over U.S. Patent 6,334,856 to Allen et al. as applied to claims 2, 27, and 32, and further in view of in view of U.S. Patent 5,364,374 to Morrison et al. (cited by Applicant).

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR

1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). For applications filed on or after November 29, 1999, this rejection might also be overcome by showing that the subject matter of the reference and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person. See MPEP § 706.02(l)(1) and § 706.02(l)(2).

Allen et al. does not teach that the collection chamber is a standard or Luer-lock syringe. Allen et al. teaches that the device can be used for removing samples. (column 17, line 60 to column 18, lines 7 of Allen et al.). Allen does teach that the flow of molecules through the microneedle can occur based on diffusion, capillary action, or induced by conventional mechanical pumps or non-mechanical driving forces. Allen et al. provides a clear suggestions that the flow of particles though the microneedle can occur through a variety of means. Allen et al. further suggests that the flow of particles can be into or out of the device. It is well known in the art that a syringe is a mechanical pump that induces a flow of particles when withdrawing fluid. Morrison et al. discloses a microneedle connected to a syringe as stated in column 2, lines 26-40. Such a mechanical pump is the type of flow inducing means that Allen et al. requires. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the microneedle device of Allen et al. include a

syringe as disclosed by Morrison et al. since Allen et al. implies that the flow of particles can be performed by mechanical pump means and Morrison et al. teaches such means.

6. Claims 3, 6, and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 6,334,856 to Allen et al. as applied to claim 2 and further in view of in view of U.S. Patent 4,703,761 to Rathbone et al. (cited by Applicant). Allen et al. does not disclose that the collection chamber comprises an upper portion which is formed of a material which is deformable. Allen et al. teaches that the device can be used for removing samples. (column 17, line 60 to column 18, lines 7 of Allen et al.). Allen does teach that the flow of molecules through the microneedle can occur based on diffusion, capillary action, or induced by conventional mechanical pumps or non-mechanical driving forces. Allen et al. provides a clear suggestions that the flow of particles though the microneedle can occur through a variety of means. Allen et al. further suggests that the flow of particles can be into or out of the device. Rathbone et al. teaches in column 1, lines 34-42 that a procedure for drawing blood involves the use of a flexible plastic bulb which is connected to a collecting tube and is manually squeezed to create negative pressure for drawing the blood sample. This device operates in a manner similar to an eye dropper. Such a mechanical pump is the type of flow inducing means that Allen et al. requires. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the microneedle device of Allen et al. include a syringe as disclosed by Rathbone et al. since Allen et al. implies that the flow of particles can be performed by mechanical pump means and Rathbone

et al. teaches such means. In regard to claim 8, one-way gate valves can be used. (column 7, lines 47-60 of Allen et al.). It is noted that the applied reference has a common inventor with the instant application so please see paragraph 4 in regards to overcoming the rejection.

7. Claim 24 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 6,334,856 to Allen et al. as applied to claim 1, and further in view of International Application Publication WO 98/00193 to Eppstein (cited by Applicant). Allen et al. does not explicitly teach the use of glucose strip inside the collection chamber. Allen et al. discloses that the fluid can be assayed while in the collection chamber (column 17, lines 60-67 of Allen et al.). Allen et al. further teaches that glucose concentration can be determined. (column 7, line 66 to column 8, line 29 of Allen et al.). It is well known in the art that glucose strips are used to determine the amount of glucose in a patient's blood. Eppstein discloses that the fluid can be analyzed according to known methods such as various test strips for glucose. (page 13, lines 28-32 of Eppstein). The use of glucose strips is the type of method that Allen et al. refers to while monitoring glucose. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Allen et al. to include the use of glucose strips as disclosed by Eppstein since Allen teaches that analytes can be monitored in the collection chamber and Eppstein teaches such a method. It is noted that the applied reference has a common inventor with the instant application so please see paragraph 4 in regards to overcoming the rejection.

Double Patenting

8. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

9. Claim 1-4, 6, 27, 29-30, 36, 38-41, and 46 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 6, and 9 of U.S. Patent No. 6,503,231 to Prausnitz et al. ('231) in view of Japanese Patent Application Publication JP07132119A to Yoshihiko (cited by Applicant). Claim 1 of '231 claims a device for transport of material or energy across biological barriers comprising: a plurality of hollow microneedles having a length between 100 microns and 1 mm; a substrate to which the microneedles are attached or integrally formed; the microneedles extending at an angle from the substrate; and wherein each microneedle has a shaft, a portion of which comprises one or more substantially annular bores or channels therethrough and which has a width between about 1 microns and 100 microns. Claim 1 of '231 does not teach a collection chamber which is selectably in fluid communication with the base end of the microneedle. Claim

1 of '231 teaches that the device is used to transport material or energy across biological barriers. Yoshihiko discloses a blood-collecting device that includes a substrate 1 with a plurality of microneedles 11 and a collection chamber (where the number 12 is located). Such an application of the microneedles would fall under the scope of a device for the transport of material or energy across biological barriers. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to use the device of '231 as a blood collection device as disclosed by Yoshihiko since claim 1 of '231 teaches that the device is used for the transport of material or energy across biological barriers and Yoshihiko teaches one such application. Claim 1 of '231 claims that the needles extend at an angle from the substrate. Claim 1 of '231 does not claim what that angle is. Yoshihiko teaches needles that are perpendicular to the substrate. (Fig. 2 of Yoshihiko). Such an angle would fall within the scope of "at an angle" as claimed in '231. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to use the device of '231 so that the needles would be perpendicular to the substrate as disclosed by Yoshihiko since claim 1 of '231 teaches that the needles extend from the substrate at an angle and Yoshihiko teaches one such angle. In regard to claims 2-4 and 6, a means for inducing flow is disclosed. (paragraph 0009 of Yoshihiko). The membrane 12 is deformed when heat is generated from the micro-heater 3, which increases the volume of the collection chamber. In claims 3 and 29, the blood is collected using a negative pressure in the collection chamber. (lines 9-10 of the constitution of Yoshihiko). In regard to claim 30, the device sucks up blood, which

inherently includes glucose, cholesterol, and hemoglobin. (paragraph 0007 of Yoshihiko). In regard to claim 36, the device is applied to the skin surface of a human being. (paragraph 0021 of Yoshihiko). In regard to claim 38, the needle comprises metal. (claim 6 of '231). In regard to claim 39, the microneedle consists essentially of a metal. (claim 9 of '231). In regard to claim 46, claim 1 of '231 claims that the shafts have widths of 1-100 microns and it is obvious to one with ordinary skill in the art that any diameter in that range would fall within the scope of the claims.

Response to Arguments

10. Applicant's arguments filed 6/17/2002 have been fully considered but they are not persuasive. The Applicant stated that the 102(e) rejections will be rectified by submission of an affidavit or declaration under 37 C.F.R. 1.132. There has been no such submission so the rejections are maintained. In regards to the Applicants other arguments regarding the 102(b) rejections, they have been fully considered but are moot in view of the new ground(s) of rejection.

Drawings

11. The corrected or substitute drawings were received on 12/26/2001. These drawings are acceptable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Matthew J Kremer whose telephone number is 703-605-

0421. The examiner can normally be reached on Mon. through Fri. between 7:30 a.m. - 4:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eric Winakur can be reached on 703-308-3940. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-0758 for regular communications and 703-308-0758 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

Matthew Kremer
Assistant Examiner
Art Unit 3736
May 12, 2003

ERIC F. WINAKUR
PRIMARY EXAMINER